

**No. 2024-1658**

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United States Court of Appeals  
for the Federal Circuit

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UNITED THERAPEUTICS CORPORATION,

*Plaintiff-Appellant,*

v.

LIQUIDIA TECHNOLOGIES, INC.,

*Defendant-Appellee.*

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*Appeal from the United States District Court for the  
District of Delaware, No. 20-755, Judge Richard Andrews*

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**DEFENDANT-APPELLEE LIQUIDIA TECHNOLOGIES, INC.'S  
RESPONSIVE BRIEF**

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## CERTIFICATE OF INTEREST

Counsel for Appellee certifies the following:

**1. The full name of every party represented by me is:**

Liquidia Technologies, Inc.

**2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:**

None.

**3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:**

Liquidia Corporation

Caligan Partners LP

**4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:**

COOLEY LLP: Sanya Sukduang, Jonathan Davies, Brittany Cazakoff

**5. The title and number of any case known to me to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal are:**

*United Therapeutics Corporation v. Liquidia Technologies, Inc.*, Nos. 2022-2217, 2023-1021 (Fed. Cir.); originating from *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1-20-cv-755 (D. Del.)

**6. Any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):**

None.

Dated: June 24, 2024

/s/ Sanya Sukduang  
Sanya Sukduang

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<b>Abbreviation</b>	<b>Term</b>
'793 patent	U.S. Patent No. 10,716,793
'793 IPR	<i>Liquidia Technologies, Inc. v. United Therapeutics Corp.</i> , No. IPR2021-00406 (P.T.A.B.)
BB	UTC's Opening Blue Brief
FDA	Food and Drug Administration
FWD	Final Written Decision
IPR	<i>Inter Partes</i> Review
Liquidia	Liquidia Technologies, Inc.
NDA	New Drug Application
PAH	Pulmonary arterial hypertension (Group 1 PH)
PH	Pulmonary hypertension
PTAB	Patent Trial and Appeal Board
PTO	United States Patent and Trademark Office
UTC	United Therapeutics Corporation

## STATEMENT OF RELATED CASES

The following cases are related to this appeal, as defined by Federal Circuit Rule 47.5(a):

*United Therapeutics Corporation v. Liquidia Technologies, Inc.*, Nos. 2022-2217, 2023-1021, 74 F.4th 1360 (Fed. Cir. July 24, 2023) (Circuit Judges Lourie, Dyk, and Stoll);

*United Therapeutics Corporation v. Liquidia Technologies, Inc.*, No. 2023-1805, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023) (Circuit Judges Lourie, Prost, and Reyna).

## **I. INTRODUCTION**

UTC's position that it is "entitled" to a prospective injunction under 35 U.S.C. § 271(e)(4)(A) is premised entirely on the false notion that the '793 patent is still valid and enforceable. It is not. And because the '793 patent has been duly determined to be invalid by the PTAB and affirmed by this Court, the district court, grounded in the statute and precedent, did not abuse its discretion, nor commit any error in law, when it granted Liquidia's Rule 60 motion and lifted the § 271(e)(4)(A) injunction previously based on the '793 patent.

There is no dispute that the '793 patent is invalid. Neither claim cancellation under 35 U.S.C. § 318, nor a pending certiorari petition before the Supreme Court changes the fact that the '793 patent is legally inoperative. And because it is invalid, no continuing, prospective injunction, whether statutory or otherwise, can be had. Accordingly, the district court properly interpreted 35 U.S.C. § 271(e)(4)(A) to require a valid patent as a predicate to a Hatch-Waxman injunction and no language in § 271(e)(4)(A), or the Hatch-Waxman Act generally, permits the outcome UTC seeks here—enjoining a company based on a finally adjudicated invalid patent.

Further, the district court properly applied issue preclusion to prevent UTC, the patent owner, from obtaining an injunction based on the invalid '793 patent. The cases cited by UTC, not surprisingly, do not examine collateral estoppel against a patent owner. Instead, these cases precluded application of collateral estoppel

against a defendant because the alleged infringer did not have a full and fair opportunity to litigate the specific invalidity defense. In contrast, here, UTC is the patentee, and collateral estoppel was properly applied by the district court because there is no scenario in which UTC can still argue the '793 patent is valid.

Finally, the equities favor affirming the district court's Rule 60(b) decision. Because a patent, by its very nature, impacts the public interest, there is a strong incentive to keep the scope of a patent's monopoly in-check. Here, because the '793 patent has been held invalid, upholding an injunction based on this patent would be *per se* inequitable and detrimental to the public interest. For the reasons expressed by the district court, and presented here, the district court's Rule 60(b) decision should be affirmed.

## **II. STATEMENT OF ISSUES PRESENTED**

1) Whether the district court exercised proper discretion and did not commit an error of law in granting Liquidia's Federal Rule of Civil Procedure Rule 60(b)(5)–(6) motion and lifting its 35 U.S.C. § 271(e)(4)(A) injunction where the district court determined:

- the '793 patent was found invalid by the PTAB, affirmed by this Court, and the mandate had issued;
- such a prospective injunction was statutorily prohibited because it requires a valid patent that can be infringed; and

- under precedent from this Court, affirmance of the PTAB’s final written decision invalidating the ’793 patent had immediate preclusive effect on UTC, the patent owner, on the co-pending litigation before the district court warranting modification of the final judgment and lifting of the § 271(e)(4)(A) injunction.

### **III. STATEMENT OF THE CASE**

In January 2020, Liquidia submitted an NDA to the FDA seeking approval to market Yutrepia™, its novel treprostinil product for the treatment of PAH. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1364 (Fed. Cir. 2023). Shortly after, UTC sued Liquidia asserting infringement of several patents, including the ’793 patent. *Id.* After trial, the Court entered judgment on September 9, 2022, finding that the asserted claims of the ’793 patent were valid and Liquidia induced infringement of those claims. Appx3654–3656. The Court also ordered that, under 35 U.S.C. § 271(e)(4)(A), “the effective date of any final approval by the FDA of Liquidia’s New Drug Application No. 213005 shall be a date which is not earlier than the expiration date of the ’793 patent.” Appx3655, ¶4. Liquidia appealed this judgment. Subsequently, this Court affirmed the district court’s decision regarding the ’793 patent on July 24, 2023. *United Therapeutics*, 74 F.4th at 1374. The Supreme Court denied Liquidia’s petition for a writ of certiorari in

February 2024. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, 144 S. Ct. 873 (2024).

While the district court action was pending, Liquidia submitted an IPR petition regarding the '793 patent on January 7, 2021. The '793 IPR was instituted, and the PTAB issued its FWD on July 19, 2022, finding all claims of the '793 patent invalid, a month before the district court rendered its decision in the parallel action. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-1805, 2023 WL 8794633, at \*1 (Fed. Cir. Dec. 20, 2023). UTC appealed the FWD to this Court, which affirmed the invalidity ruling in a non-precedential opinion issued on December 20, 2023. *Id.* at \*3–6. UTC's petitions for panel rehearing and rehearing en banc were denied, and the mandate issued to the PTAB on March 19, 2024. Appx4441–Appx4444.

On December 26, 2023, shortly after this Court's decision affirming the '793 patent invalidation in the IPR and before the Supreme Court denied Liquidia's certiorari petition, Liquidia filed its motion for post-judgment relief under Rule 60(b), requesting the district court lift its § 271(e)(4)(A) injunction. Appx4257–4269. UTC opposed, and Liquidia filed its reply on January 23, 2024. Appx4395–4410. Briefing on Liquidia's Rule 60(b) motion was complete by January 2024, prior to the Supreme Court's February 2024 denial of Liquidia's certiorari petition. The district court granted Liquidia's Rule 60(b) motion on March 28, 2024 and

issued an Amended Judgment on the same day. Appx1–5; Appx6–9. In granting Liquidia’s Rule 60(b) motion, the district court recognized that § 271(e)(4)(A) “requires an infringed patent in the first place. Invalid patents cannot be infringed.” Appx5.

UTC, on April 1, 2024, then moved to stay entry of the Amended Judgment before the district court. Appx4452–4456; Appx4457–4462. Liquidia opposed. Appx4476–4514. The district court denied UTC’s motion to stay on April 17, 2024. Appx4515–4518. Subsequently, UTC filed a motion before this Court seeking to stay entry of the amended judgement pending appeal. Dkt. 10. UTC’s motion was denied on May 9, 2024. Dkt. 16.

#### **IV. SUMMARY OF ARGUMENT**

1. The ’793 patent is invalid. As a result, and under a plain reading of 35 U.S.C. § 271(e)(4)(A), and the Hatch-Waxman Act generally, an invalid patent cannot be the foundation of a statutory injunction. This holds true even though the PTO Director has not yet concluded the ministerial act of cancelling the ’793 patent claims under 35 U.S.C. § 318.

2. The district court properly exercised its discretion under Federal Rule of Civil Procedure 60(b)(5) and 60(b)(6) to lift the § 271(e)(4)(A) injunction against Liquidia because issue preclusion prevents UTC, the patent owner, from re-litigating the validity of the ’793 patent. To be clear, when considering a prospective remedy,

like an injunction (statutory or otherwise), a district court *always* has discretion to modify its judgment. While that discretion might be limited when the judgment relates to monetary damages, the Court need not concern itself with that issue here. Moreover, whether validity is considered a single issue or not is immaterial here because there is simply no room for patent owner UTC to argue that the '793 patent is still valid and escape the effects of collateral estoppel. That an alleged infringer may parse invalidity defenses to avoid application of collateral estoppel, as the case law UTC cites suggests, is not surprising. Of course it is true that a finding that a patent is not invalid under one theory does not mean that the patent is not invalid under another theory. However, it is not applicable here. UTC is not the accused infringer; it is the patent owner. If a patent is found to be invalid under any theory of invalidity, then it remains invalid even if it is not invalid under all theories of invalidity.

3. Liquidia's decision to file a successful IPR against the '793 patent does not prevent the district court from relying on this Court's affirmance of the PTAB's decision in granting Rule 60(b) relief. Indeed, nothing in § 271(e)(4)(A) nor Rule 60(b) expressly or implicitly forecloses relief under the facts presented here. In fact, and as discussed below, this Court's prior decision in *Prism* reached the same conclusion, applying collateral estoppel against patent owner Prism based on a



subsequent PTAB decision, despite the fact that the alleged infringer gave up arguing invalidity at trial.

4. Finally, the equities favor affirming the district court’s decision. Congress did not determine that a § 271(e)(4)(A) injunction can be maintained unless and until patent claims are cancelled under 35 U.S.C. § 318. In fact, Section 271(e)(4)(A) makes no mention of claim cancelation and, importantly, Congress would have no reason to balance the equities in the manner UTC suggests because patents grant a limited monopoly that, by definition, affects the public interest. That monopoly must be kept within its acceptable bounds and necessarily excludes maintaining a monopolistic injunction based on a finally adjudicated invalid patent.

## **V. ARGUMENT**

### **A. Standard of Review**

“Rule 60(b) authorizes a court to grant relief from a final judgment if ‘applying [the order] prospectively is no longer equitable’ or for ‘any other reason that justifies relief.’” *In re Linerboard Antitrust Litig.*, 361 F. App’x 392, 397 (3d Cir. 2010) (quoting Fed. R. Civ. P. 60(b)(5)–(6)). Relief under Rule 60(b)(5) is warranted if “the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable[.]” Fed. R. Civ. P. 60(b)(5). It allows a party to ask a court to modify or vacate a judgment if a significant change either in facts or in law “renders

continued enforcement ‘detrimental to the public interest.’” *Horne v. Flores*, 557 U.S. 433, 447 (2009) (quoting *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 384 (1992)). The Supreme Court has ruled that “it is appropriate to grant a Rule 60(b)(5) motion when the party seeking relief from an injunction or consent decree can show ‘a significant change either in factual conditions or in law.’” *Agostini v. Felton*, 521 U.S. 203, 215 (1997) (quoting *Rufo*, 502 U.S. at 384).

Rule 60(b)(6) is a “catchall provision” that enables courts to vacate judgments whenever such action is appropriate to accomplish justice, though only in extraordinary circumstances. *Forest Lab ’ys, LLC v. Sigmapharm Lab ’ys, LLC*, Civ. No. 14-1119-MSG, 2019 WL 3574249 at \*5 (D. Del. Aug. 6, 2019); *see also Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 863–64 (1988). Extraordinary circumstances are those “where, without such relief, an extreme and unexpected hardship would occur.” *Cox v. Horn*, 757 F.3d 113, 120 (3d Cir. 2014) (citation omitted).

Relief under Rule 60(b) is a procedural issue on which this Court applies regional circuit law. *Cap Exp., LLC v. Zinus, Inc.*, 996 F.3d 1332, 1338 (Fed. Cir. 2021); *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1069 (Fed. Cir. 2024). In the Third Circuit, a district court’s decision to grant Rule 60(b) relief is reviewed for abuse of discretion. *See Sovereign Bank v. REMI Cap., Inc.*, 49 F.4th 360, 364 (3d Cir. 2022) (quoting *Budget Blinds, Inc. v. White*, 536 F.3d 244, 251 (3d

Cir. 2008)); *In re Linerboard*, 361 F. App'x at 395, 398; *Cox*, 757 F.3d at 118. However, to the extent statutory interpretation is required, this Court does so without deference to the district court. *See Salix*, 98 F.4th 1067. But the Court, when interpreting a statute, cannot be guided by a single sentence, but instead must look to “provisions of the whole law, and to its object and policy.” *Id.* (quoting, *U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993)).

### **B. The '793 Is Invalid and No Longer Enforceable**

UTC's appeal rests entirely on the false notion that the '793 patent is still valid and can be enforced, going so far as to assert that “here, there is a ‘patent which has been infringed’[.]” BB15; *see also* BB13 (stating the '793 patent remains “in force”). Not so, because an invalid patent cannot be infringed. There is no dispute that the PTAB determined all claims of the '793 patent are unpatentable and that the PTAB's decision was affirmed by this Court. Appx3550–3598; *United Therapeutics Corp.*, 2023 WL 8794633, at \*1. Further, UTC sought panel and en banc rehearing of this Court's decision, both of which were denied, and the Court's mandate issued to the PTAB. Appx4435–4439; Appx4444. Although UTC filed for certiorari before the Supreme Court,<sup>1</sup> it does not change the fact that the '793 patent is invalid,

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<sup>1</sup> UTC's certiorari petition was filed on June 10, 2024, and the Court has indicated this appeal will be set for the September calendar. *See* Dkt. 16. In the likely event the Supreme Court denies certiorari, UTC's appeal will become moot because the PTO Director will cancel the '793 patent claims.

no longer enforceable, and cannot form the basis for an injunction, statutory or otherwise. *See ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1354–55 (Fed. Cir. 2015) (“It is well established that an injunction must be set aside when the legal basis for it has ceased to exist.”); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1578 (Fed. Cir. 1994) (recognizing that upholding an injunction based on a patent would be at odds with the Court’s historical treatment of patents it recently declared invalid); *U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.*, 645 F. App’x 1026, 1029 (Fed. Cir. 2016) (applying preclusion, holding “[t]he invalidity of the ’827 patent has been adjudged—to enforce it against TI in light of our concurrent affirmance in *Acer* would thus extend the patent beyond its proper scope.”); *John Simmons Co. v. Grier Bros. Co.*, 258 U.S. 82, 88 (1922) (finding that the district court must apply intervening legal developments affecting the asserted patent’s validity, even if the court of appeals already decided the validity issue the other way).

That the ’793 patent is invalid and no longer enforceable is established under precedent from this Court and confirmed by UTC’s own actions concerning the ’793 patent. First, once this Court affirmed the PTAB’s ’793 patent FWD, UTC was *immediately* estopped from further asserting the ’793 patent against Liquidia and any other party because it is invalid. *See XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018) (finding that the Federal Circuit’s affirmance rendering final a PTAB judgment of invalidity had an immediate preclusive effect on other

pending actions involving the patent); *Prism Techs. LLC v. Sprint Spectrum, L.P.*, 757 F. App'x 980, 987–88 (Fed. Cir. 2019). In *XY*, Trans Ova was found to have infringed the asserted “Freezing Patent” claims and those claims were found valid. 890 F.3d at 1288. On appeal, this Court determined that XY, the patent owner, was collaterally estopped from asserting the Freezing Patents because, in a separate case, the Court affirmed a PTAB’s FWD of invalidity of the same asserted claims. *Id.* at 1294. As this Court explained, “[t]hat affirmance *renders final a judgment on the invalidity* of the Freezing Patents,” and “an affirmance of an invalidity finding, whether from a district court or the Board, has a collateral estoppel effect on all pending or co-pending actions.” *Id.* (emphasis added). To be clear, this Court considered an affirmance of a PTAB FWD in an IPR to be a decision of sufficient “finality,” to apply collateral estoppel against a patent owner, even without claim cancellation under 35 U.S.C. § 318(b).

Additionally, in *Prism*, which addressed a district court’s grant of a Rule 60 motion, the Court had previously affirmed the district court’s decision that Sprint infringed Prism’s asserted patent claims. *Prism*, 757 F. App'x at 987. But, in a separate proceeding between Prism and T-Mobile, this Court held that the same asserted claims were invalid. *Prism*, 757 F. App'x at 986–87. Sprint then sought relief under Rule 60(b)(6), which the district court properly granted given that the asserted claims were invalid and this Court later affirmed. *Id.* at 982–983, 987.

Importantly, Sprint had “dropped its invalidity challenges just before trial[,]” and Prism argued, based on Sprint’s actions, that Sprint cannot use that later invalidity ruling as a basis to modify the judgment under Rule 60. *Id.* at 987–88. The Court disagreed, noting that Prism, the patent owner, identified no precedent warranting deviation from the long-standing federal policy against enforcing a judgment of patent liability when that patent had been held invalid in a separate proceeding. *Id.* This Court’s precedent makes clear that regardless of whether this Court affirms an invalidity finding from a district court or the PTAB, the impact is the same—the patentee is immediately estopped from asserting the patent.

Second, UTC’s own actions confirm the ’793 patent cannot be enforced. Before the district court, and relying on *XY*, UTC stated that “[c]onsistent with the Federal Circuit’s guidance, district courts do not apply collateral estoppel effect to the PTAB’s ruling *until the ruling is affirmed*[.]” Appx4519–4520 (emphasis added). UTC put those words into action with respect to the ’793 patent. Specifically, on September 5, 2023, UTC filed a Complaint asserting the ’793 patent against Liquidia and re-asserted the ’793 patent on November 20, 2023, in its Amended Complaint. *See* Dkt. 13, Ex. 1 at 1–3. However, on January 22, 2024, shortly after this Court’s affirmance of the PTAB’s ’793 patent FWD, UTC voluntarily dismissed its ’793 infringement claims against Liquidia. *Id.* UTC dismissed its ’793 complaint despite the fact that its request for rehearing en banc

was pending (filed on January 19, 2024), the Court had not issued its mandate, the PTO Director had not yet cancelled the '793 patent claims, and the '793 patent had not been de-listed from the Orange Book. As UTC recognized, because the PTAB's FWD invalidating all claims of the '793 patent has been affirmed, the '793 patent is invalid and can no longer be enforced by UTC. Thus, UTC's contention that the '793 patent "remains in force[,]" and continues to provide "a potential basis for suit under § 271(e)(2) and a statutory order under § 271(e)(4)(A)—until all appeals are exhausted and the claims are cancelled[," is simply incorrect. BB13, 23. Indeed, if UTC truly believed its own rhetoric, it would have never dismissed its later filed '793 patent infringement suit against Liquidia. Because the '793 patent is invalid, it cannot provide the basis for an injunction under any circumstance.

**C. The District Court Interpreted 35 U.S.C. § 271(e) Correctly**

**1. Section 271(e)(4)(A) requires a valid patent**

Leaning heavily on the Hatch-Waxman Act, UTC asserts that § 271(e)(4)(A) not only "compels" the district court to enter an injunction based on the '793 patent, but also *maintain* that injunction even when the '793 patent has been invalidated. BB13–24. No statute, let alone § 271(e)(4)(A), can be read to compel any court to enter and maintain an injunction based on an invalid patent. The Supreme Court has made clear that "[a] patent by its very nature is affected with a public interest" and "[t]he far-reaching social and economic consequences of a patent, therefore, give the

public a paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.” *Blonder-Tongue Lab’ys, Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 343 (1971) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). Consistent with this edict, this Court has recognized that upholding an injunction would be “anomalous in the extreme in connection with patents this court has just held invalid[,]” because that would improperly extend the “legitimate scope” of the patent. *Mendenhall*, 26 F.3d at 1578; *see also ePlus*, 789 F.3d at 1354–55; *U.S. Ethernet*, 645 F. App’x at 1029.

Here, reading the plain language of § 271(e)(4)(A), the district court correctly determined that “the statute requires an infringed patent in the first place. Invalid patents cannot be infringed.” Appx4–5. And the district court was correct as the Supreme Court has explained that “[t]o be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.” *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 644 (2015).

The district court’s ruling is grounded in the plain language of § 271(e). Section 271(e)(2)(A) states: “It shall be an act of infringement to submit– an application . . . described in section 505(b)(2) of such Act for a drug claimed ***in a patent*** or the use of which is claimed ***in a patent***[.]” 35 U.S.C. § 271(e)(2) (emphasis added). As the Court is aware, the act of infringement set forth in § 271(e)(2) is



“artificial,” and a district court is required to determine whether under § 271(a)–(c) the proposed product infringes the patent. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Par Pharm., Inc. v. Eagle Pharms., Inc.* 44 F.4th 1379, 1383 (Fed. Cir. 2022) (“[C]ourts must conduct an inquiry to determine whether the probable [505(b)(2)] product would infringe once it is made, used, or sold”); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365–66 (Fed. Cir. 2003) (“[A]n ‘artificial’ act of infringement creates case-or-controversy jurisdiction. . . . Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed.”) (citation omitted). Thus, simply filing a § 505(b)(2) application is not, as UTC suggests, the “relevant” act of infringement. BB14–17. Instead, the district court must determine whether the accused product that Liquidia intends to sell infringes the “patent” that is subject to § 271(e), and that patent must be valid otherwise, by law, it cannot be infringed. *See Commil*, 575 U.S. at 644.

Section 271(e)(4)(A) goes on to state that: “For an act of infringement described in paragraph (2)— the court shall order the effective date of any approval

of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration *of the patent which has been infringed*[.]” 35 U.S.C. § 271(e)(4)(A) (emphasis added). Thus, in order to enter an injunction, a valid patent must be infringed. Indeed, in this case, the district court first determined that Liquidia had infringed another asserted patent, U.S. Patent No. 9,593,066. *See* Appx3609–3610 (“I find that UTC has proven that Liquidia will meet the impurities limitations of claim 1.[ ] I therefore find that UTC has proven by a preponderance of the evidence that Liquidia’s proposed LIQ861 product will infringe claims 1, 2, and 3 of the ’066 patent.”). The district court further stated in footnote 7, relying on Supreme Court precedent, that “[s]ince I ultimately conclude that claims 1, 2, and 3 of the ’066 patent are invalid as anticipated, there is ultimately no infringement.” Appx3610 n.7. Following UTC’s rationale, where there is “no room for discretion” to enter an injunction upon a finding of infringement, the district court would have been required to enjoin Liquidia under the ’066 patent because it was infringed. BB14–17. Of course, that is the incorrect interpretation of § 271(e)(4)(A) and importantly, UTC did not argue on appeal that the district court committed legal error by failing to enjoin Liquidia under § 271(e)(4)(A), who had been found to infringe the ’066 patent. The district court’s Rule 60 decision is consistent with its decision concerning the simultaneously asserted ’066 patent and was correct that a

Hatch-Waxman injunction can only be ordered if the patent holder obtains a finding of infringement of a *valid* patent. The district court committed no legal error.

## **2. Section 271(e) does not require claim cancellation**

UTC asserts that the district court is not authorized to modify its prior judgment “based upon a collateral administrative proceeding that has not resulted in cancellation of the patent.” BB16–24. But nothing in § 271(e)(4)(A) requires claim cancellation as UTC suggests, and UTC cites no case prohibiting the district court from exercising its discretion to lift its prior prospective injunction. More pertinent, UTC cites no case where claim cancellation under 35 U.S.C. § 318(b) was required in order to modify a Hatch-Waxman injunction pursuant to Rule 60(b).

UTC makes more of § 318(b)’s ministerial formality than what it is. BB17, 20. Claim cancellation does not make a patent invalid; a judgment of invalidity—which has already occurred here—does. This Court has held that “cancellation” of a patent under § 318(b) is a “nondiscretionary formality[,]” that does not affect the binding effects of the decision itself. *Security People, Inc. v. Iancu*, 971 F.3d 1355, 1361 (Fed. Cir. 2020) (citing 35 U.S.C. § 318(b)). For purposes of judicial review, for instance, “the certificate of cancellation is irrelevant to the finality of the agency’s action, as no agency decision-making is involved in deciding to issue the certificate.” *Id.* Indeed, in *XY*, the Federal Circuit dismissed a co-pending appeal on the same day it issued its affirmance of the PTAB’s FWD decision on that same

patent—it did not wait for claim cancellation. *XY*, 890 F.3d at 1294. Similarly, UTC dismissed its new '793 patent infringement allegations against Liquidia without waiting for claim cancellation under § 318. *See supra* § VI.B. Maintaining that an agency's ministerial act of claim cancellation is necessary for a patent owner to be estopped from asserting infringement of an invalid patent is not only inconsistent with UTC's own actions, but also undermines both the PTAB's authority and the effect of the Federal Circuit's decision affirming a FWD.

UTC's identification of four examples where the PTO determined that it had prematurely cancelled claims while certiorari was pending prove nothing more than the fact that the PTAB, here, might not cancel the '793 patent claims until the Supreme Court denies UTC's certiorari petition. BB21–24. Those examples do not establish the validity of the patent at issue until cancelation occurs, nor to the district court's proper interpretation of § 271(e)(4)(A) and its determination, under Rule 60(b), to modify its judgment and lift the '793 patent Hatch-Waxman injunction.

Finally, UTC's reliance on the Orange Book Transparency Act of 2020 is misplaced, as it only addresses when patents have to be de-listed from the Orange Book. BB23–24. De-listing of a patent from the Orange Book is not, however, a pre-requisite for final FDA approval of Liquidia's NDA, nor is it required to lift the district court's Hatch-Waxman injunction. Moreover, UTC's reliance on 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) to support its contention that the district court could not

lift the Hatch-Waxman injunction until “all available appeals[,]” including petitioning the Supreme Court, have been exhausted is also incorrect. BB23–24. Section 355(j)(5)(D)(i)(I)(bb)(AA), which UTC contends carves out Supreme Court review, is directed to forfeiture of an ANDA applicant’s 180-day exclusivity period. Section 355(c)(3)(C)(ii)(I)(aa), however, is directed to obtaining final FDA approval (the issue here) and permits final FDA approval upon this Court’s determination of invalidity. *See also*, 21 U.S.C. § 355(j)(5)(B)(iii)(II)(aa)(AA). This section does not include language “carving out” Supreme Court review as contained in § 355(j)(5)(D)(i)(I)(bb)(AA) but instead permits final FDA approval **before** “all available appeals” have been exhausted. *See* 21 U.S.C. § 355(c)(3)(C)(ii)(I)(aa). Nonetheless, even under § 355(c)(3)(C)(i) and § 355(c)(3)(C)(i)(I) (permitting final FDA approval on the date the district court determines the asserted patent is not infringed), the district court’s Rule 60 decision was proper because it determined that Liquidia could not infringe an invalid patent. *See* Appx4–5. Thus, the district court was correct that it did not have to wait for the Supreme Court or claim cancellation under § 318(b) to grant relief in Liquidia’s favor under Rule 60. Appx1–5.

**D. The District Court Properly Granted Liquidia’s Requested Relief Under Rule 60(b)**

**1. The Hatch-Waxman injunction was not “immune” from Rule 60(b) relief**

On the faulty assertion that the district court action concerning the ’793 patent was no longer “pending,” UTC contends that the district court could not grant Liquidia’s requested Rule 60(b) relief because this Court’s affirmance of infringement and validity of the ’793 patent rendered the § 271(e)(4)(A) injunction “immune” from further proceedings. BB25–28. Not so. The district court was well within its discretionary authority to modify its prospective Hatch-Waxman injunction in light of the ’793 patent’s invalidation. *See John Simmons*, 258 U.S. at 88 (finding that the district court must apply intervening legal developments affecting the asserted patent’s validity). Further, UTC’s position lacks merit because: (1) UTC’s cited cases pertain to monetary damages, not injunctions as at-issue here; (2) UTC’s position runs directly counter to the basic patent law principle that an injunction cannot be based on an invalid patent; and (3) there were further issues to be resolved before the district court post-mandate.

Here, Liquidia sought Rule 60(b) relief to lift an injunction. UTC’s cited cases do not save its argument as those cases address monetary judgments, not injunctions. BB25–28. In *Fresenius USA, Inc. v. Baxter International, Inc.*, 721 F.3d 1330 (Fed. Cir. 2013), the patent in question (the ’434 patent), had expired and thus the

“permanent injunction was no longer an issue[,]” and the Court’s decision on finality concerned monetary damages. *Id.* at 1333. In fact, the *Fresenius* court specifically found that “the cancellation of a patent’s claims cannot be used to reopen a final **damages judgment** ending a suit based on those claims.” *Id.* at 1340 (emphasis added). And in support, the *Fresenius* decision cited Supreme Court precedent holding “title to these moneys does not depend upon the patent, but upon . . . the judgment of the Court.” *Id.* (quoting *Moffitt v. Garr*, 66 U.S. 273, 283 (1861)). Similarly, in *WesternGeco L.L.C. v. ION Geophysical Corp.*, this Court determined that a “reasonable royalty award constitutes a fully satisfied and unappealable final judgment such that the subsequent invalidation of asserted patent claims does not support reopening.” 913 F.3d 1067, 1072 (Fed. Cir. 2019). Monetary damages, not an injunction, were also at issue in *Packet Intelligence LLC v. NetScout Systems, Inc.*, 100 F.4th 1378, 1380–81 (Fed. Cir. 2024), and the Court assessed “finality” in the particular procedural posture there. And in *Versata Software, Inc. v. SAP America, Inc.*, No. 2:07cv153-RSP, 2014 WL 1600327, at \*1–2 (E.D. Tex. Apr. 21, 2014), which also solely dealt with monetary damages, the district court denied Rule 60(b) relief seeking to modify post-judgment interest stating Rule 60(b)(5) “is clearly aimed at judgments containing injunctive relief[,]” and Rule 60(b)(6) is inapplicable because the Covered Business Method proceeding before the PTAB was not yet final, as it does not appear to have yet been affirmed on appeal. *Id.*

The distinction between a judgment for damages and a judgment imposing a permanent injunction, to use UTC’s own words, “is critical[.]” BB26. There can be no dispute that an injunction cannot be based on a patent that has been found invalid. *See ePlus*, 789 F.3d at 1354–55 (“It is well established that an injunction must be set aside when the legal basis for it has ceased to exist.”); *Mendenhall*, 26 F.3d at 1578 (recognizing that upholding an injunction based on a patent would be “anomalous in the extreme” with respect to a patent it recently declared invalid). In *ePlus*, which addressed a permanent injunction like that at issue here, this Court pointed to Supreme Court precedent for the proposition that “an injunction ‘is executory, a continuing decree . . . . If, in the mean[.]time, since the decree, this right has been modified by the competent authority . . . it is quite plain the decree of the court cannot be enforced.’” 789 F.3d at 1355 (quoting *Pennsylvania v. Wheeling & Belmont Bridge Co.*, 59 U.S. 421, 431–32 (1851)). Further, this Court stated “the fact that ‘[a] continuing decree of injunction directed to events to come is subject *always* to adaptation as events may shape the need . . . . [A] court does not abdicate its power to revoke or modify its mandate, if satisfied that what it has been doing has been turned through changing circumstances into an instrument of wrong.” *Id.* (emphasis added) (quoting *United States v. Swift & Co.*, 286 U.S. 106, 114–15 (1932)). And with respect to patent injunctions, *ePlus* recognized “[o]ur court has applied these



principles to an injunction barring infringement of patents later found to be invalid.” *Id.* (citing *Mendenhall*, 26 F.3d at 1584).

These principles also render UTC’s reliance on *In re Swanson*, 540 F.3d 1368 (Fed. Cir. 2008) inapposite. BB28. A footnote in *In re Swanson* stated that “an attempt to reopen a final federal court *judgment of infringement* on the basis of a reexamination finding of invalidity might raise constitutional problems.” 540 F.3d at 1379 n.5 (emphasis added). Here, Liquidia did not seek to modify the district court’s determination of infringement of the ’793 patent, but instead its § 271(e)(4)(A) ongoing injunction, which this Court’s precedent has determined is proper. Because the district court’s § 271(e)(4)(A) injunction is a “continuing decree,” unlike monetary damages which are satisfied, the district soundly exercised its discretion under Rule 60(b) to lift that injunction upon invalidation of the ’793 patent.

UTC is also wrong that the case was no longer pending. There were still issues to resolve before the district court, even after this Court’s October 2, 2023 mandate issued. In particular, Liquidia filed a motion to stay entry of the district court’s Hatch-Waxman injunction on September 9, 2022, before the mandate issued, which the district court did not decide until December 15, 2023, *after* the mandate. Appx3657–3660; Appx4254–4256. Thus, there were other, substantive matters to

resolve “other than [to] execute the judgment” (BB27 (citation omitted)), and the case was still pending.

Under UTC’s own reasoning, the case was not final. On appeal now, UTC principally argues that, even though the Court’s mandate to the PTAB has issued, this Court’s affirmance of the PTAB’s FWD invalidating the ’793 patent is not “final” because UTC filed a certiorari petition to the Supreme Court. BB13–24. UTC’s position is inconsistent with its position in the district court action. There, it argues the action was final and immune from post-judgment relief because the mandate had issued (BB25–26) even though, on January 23, 2024, Liquidia filed a petition for certiorari, seeking review of this Court’s affirmance of the district court’s decision concerning the ’793 patent. Appx4565-4787. UTC cannot have it both ways. And particularly so with respect to the mandate before the PTAB, as there are truly “no further issues [] left to be resolved” (BB26) at the PTAB because claim cancellation, post-mandate, is nothing more than a “nondiscretionary formality[.]” *Security People*, 971 F.3d at 1361.

Moreover, an appellate court’s affirmance does not render the district court incapable from considering events that occur after the mandate. *See Standard Oil Co. of Cal. v. United States*, 429 U.S. 17, 18–19 (1976). Here, the PTAB’s unpatentability decision was not affirmed until after this Court’s affirmance of infringement and validity of the ’793 patent, and the district court then considered

its impact on infringement when it could. *See John Simmons*, 258 U.S. at 88 (finding that the district court must apply intervening legal developments affecting the asserted patent’s validity, even if the court of appeals already decided the validity issue the other way).

As put simply by this Court, an injunction “is subject *always* to adaptation as events may shape the need,” and the district court’s inherent powers under Rule 60(b) to modify its injunction were not abrogated by this Court’s mandate. *ePlus*, 789 F.3d at 1355 (emphasis added) (quoting *Swift*, 286 U.S. at 114–15). The district court’s Rule 60(b) decision warrants affirmance.

## 2. Issue preclusion applies here

UTC’s “issue preclusion” argument is based on a fundamental misunderstanding as to whom collateral estoppel applies. Here, UTC, *as the patent owner*, is barred under collateral estoppel from re-litigating the validity of the ’793 patent, regardless of whether validity is a single issue or not, because the ’793 patent has been finally adjudicated to be invalid. BB29–33; *XY*, 890 F.3d at 1294; *Prism*, 757 F. App’x at 987. Thus, the district court properly applied this Court’s precedent in granting relief under Rule 60(b).

UTC relies only on cases where a court refused to apply collateral estoppel against an alleged infringer/defendant. BB29–33. But the question before the district court was not whether Liquidia is collaterally estopped, but whether UTC is,

and the answer is “yes.” In *Orexo AB v. Actavis Elizabeth LLC*, 371 F. Supp. 3d 175 (D. Del. 2019), a non-binding district court decision, the alleged infringer in a prior litigation argued the asserted patent was invalid as obvious but lost that issue before the district court. *Id.* at 179. Based on that prior decision, Orexo, the patent owner, filed for summary judgment seeking to preclude the alleged infringer from litigating invalidity, on any ground, under the principle of collateral estoppel. *Id.* at 180–81. The district court in *Orexo* determined that collateral estoppel did not apply to the alleged infringer because other invalidity arguments, such as § 112 positions, were not previously litigated and thus the prior adjudicated invalidity defense was “not identical to the invalidity defense Defendants seek to present in this action[.]”<sup>2</sup> *Id.* at 186–87. In *Voter Verified, Inc. v. Election Systems & Software LLC*, 887 F.3d 1376 (Fed. Cir. 2018), collateral estoppel again did not apply to the alleged infringer, Election Systems, because the § 101 invalidity position Election Systems was taking “was not actually litigated and it was not necessary to the judgment rendered” in the prior case. *Id.* at 1383–84; *see also TASER Int’l Inc. v. Karbon Arms, LLC*, 6 F. Supp. 3d 510, 519–20 (D. Del. 2013) (refusing to apply collateral estoppel against

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<sup>2</sup> The district court also noted that “the overwhelming majority of court opinions support Orexo’s position” that validity is a single issue, as opposed to UTC’s multiple issues argument here. *See Orexo*, 371 F. Supp. 3d at 184. Whether validity is a single issue or not, however, is immaterial here because collateral estoppel is being applied against patent owner, UTC.

the alleged infringer because different invalidity arguments were being presented); *Sprint Commc'ns Co. v. Charter Commc'ns, Inc.*, No. 17-1734-RGA, 2021 WL 982726, at \*7 (D. Del. Mar. 16, 2021) (refusing to apply collateral estoppel against alleged infringer because the § 112 defenses presented are based on a new claim construction and thus the issue was not previously litigated); *PureWick Corp. v. Sage Prods., LLC*, No. 22-102-MN, 2023 WL 2734779, at \*6, \*8 (D. Del. Mar. 31, 2023) (refusing to apply collateral estoppel against alleged infringer because the invalidity issue was not previously litigated). These cases are inapplicable here because they do not address when a patent owner, like UTC, is collaterally estopped from re-litigating validity.

In contrast, this Court's decision in *Ohio Willow Woods* establishes the propriety of applying collateral estoppel to the patent owner. There, in an earlier Thermo-Ply litigation, the patent at issue was found to be invalid. *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1341 (Fed. Cir. 2013). Based on that prior decision, a district court in a separate proceeding granted summary judgment that a different but related patent was invalid due to collateral estoppel and prevented the patent owner from proceeding. *Id.* This Court affirmed and applied collateral estoppel to the patent owner as it has repeatedly done. *See, e.g., Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys, Inc.*, 774 F. App'x 679 (Fed. Cir. 2019) (reversing judgment of infringement where asserted patents were

invalid); *O2 Micro Int'l Ltd. v. Taiwan Sumida Elecs., Inc.*, 315 F. App'x 266 (Fed. Cir. 2009) (explaining the Court's judgment of invalidity collaterally estops patent owner from pursuing infringement claims); *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1374, 1382 (Fed. Cir. 1999) (affirming the district court's grant of collateral estoppel against patent owner from asserting infringement claim based on a judgment of invalidity and unenforceability); *Mendenhall*, 26 F.3d at 1578 ("Because its patents are invalid and were determined to be invalid after full and fair litigation, [patent owner] is collaterally estopped from recovering for infringement of those patents in these pending cases").

UTC also asserts that *XY* was silent on "the issue of identity" because it was undisputed that issue preclusion applied. BB31. What UTC overlooks, however, is that in *XY* there was no dispute that collateral estoppel applied to the patent owner because the patent was found invalid. Indeed, this Court stated collateral estoppel applied because "a *patentee*, having been afforded the opportunity to exhaust his remedy of appeal from a holding of invalidity, has had his 'day in court,' and a defendant should not have to continue 'defend[ing] a suit for infringement of [an] adjudged invalid patent.'" *XY*, 890 F.3d at 1294 (emphasis added) (quoting *U.S. Ethernet*, 645 F. App'x at 1028–30). *XY* also undermines UTC's different burdens of proof argument (BB33) because collateral estoppel in *XY* was based on an IPR decision. See also *Fresenius*, 721 F.3d at 1344 ("[T]here

is no basis for distinguishing between the effects of a final, affirmed court decision determining invalidity and a final, affirmed PTO decision determining invalidity on a pending litigation.”).

In sum, UTC cites no case where a *patent owner* avoided application of collateral estoppel permitting it to re-litigate the issue of validity of a patent that has been found invalid. Moreover, as this Court has explained, “the defense of collateral estoppel based on a final judgment of patent invalidity in another suit can be timely made at any stage of the affected proceedings.” *Mendenhall*, 26 F.3d at 1579 (internal quotation marks omitted) (citation omitted). Accordingly, the district court properly applied this Court’s precedent in granting Rule 60(b) relief.

### **3. The Hatch-Waxman statute does not abrogate a district court’s discretion to grant relief under Rule 60(b)**

In an effort to seek *de novo* review, UTC contends the district court had no “discretion to depart from the mandatory § 271(e)(4)(A) remedy while the [’793] patent remains listed[]” in the Orange Book. BB33–36, 34. UTC does not, however support this statement in its substantive argument and, in fact, makes no further mention of Orange Book listing. BB34–36. This is not surprising because UTC is incorrect. Orange Book listing is not the determining factor—patent invalidity is. *See supra*, § VI.C. Indeed, nothing in the plain language of § 271(e)(4)(A) dictates that the injunction stands while the patent-at-issue remains listed in the Orange Book, and UTC cites no relevant case or legislative history supporting its newly

made argument that the Hatch-Waxman Act precludes a district court from granting relief under Rule 60(b), thereby warranting *de novo* review. Here, the district court was well within its discretion in granting relief to Liquidia.

UTC's reliance on *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432 (1999) exposes the fallacy of its "no discretion" argument. In *Hughes*, the Supreme Court stated the well-known principle that "[a]s in any case of statutory construction, our analysis begins with 'the language of the statute.'" *Id.* at 438 (quoting *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992)). And in the portion of *Hughes* cited by UTC, the Supreme Court pointed to the ERISA statute stating "ERISA itself *plainly spells out the circumstances*" concerning the case and denied relief based on this plain language. *Id.* at 446-447 (emphasis added). Tellingly, UTC does not point to language in § 271(e)(4)(A) specifically, or § 271(e) generally, to provide support for its statutory interpretation that (1) § 271(e)(4)(A) removes any discretion under Rule 60(b)(5) or (b)(6); or (2) that Rule 60(b) relief is statutorily precluded until the '793 patent is de-listed from the Orange Book. BB34–36. There is none.

Similarly, *Mobil Oil Corp. v. Higginbotham*, 436 U.S. 618 (1978), and the other cases cited by UTC address where Congress specifically acted. *See Dunning v. United States*, 232 F. Supp. 915, 927 (W.D. Mo. 1964) (the court citing a law review article, not statute or legislative history, where the author "presume[d]"



Congress weighed the equities), *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496–97 (2001) (stating the “Controlled Substances Act vests district courts with jurisdiction to enjoin violations of the Act, 21 U.S.C. § 882(a).”), *Arizona v. California*, 460 U.S. 605, 616 (1983) (indicating Congress spoke to the water rights allocation issues specifically in the Project Act and the creation of Reservations). Indeed, *Mobil Oil* states that although acts may not address every issue, “when it does speak directly to a question, the courts are not free to ‘supplement’ Congress’ answer so thoroughly that the [a]ct becomes meaningless.” *Mobil Oil*, 436 U.S. at 625. Here, UTC alleges that Congress “already balanced the equities” and requires “an order barring FDA approval ***following a finding of infringement until the patent expires.***” BB35 (emphasis added). But Congress said no such thing and made no such balancing decision. Unlike the specific statutes addressing the specific issues in the cases cited by UTC, nothing in the Hatch-Waxman Act speaks directly to the issue of precluding relief from a § 271(e)(4)(A) injunction under Rule 60(b). What is clear, and as the district court properly concluded based on a reading of § 271(e)(4)(A), the “mandatory” injunction requires more than a finding of infringement as UTC suggests, it requires a valid patent. Appx4–5. As such, if the patent is found invalid, the injunction cannot remain until patent expiration. *See ePlus*, 789 F.3d at 1354; *see also* § 355(c)(3)(C)(ii)(I)(aa)

(permitting FDA approval upon a finding of invalidity, as opposed to patent expiry or patent de-listing).

**E. Liquidia’s Decision to File the ’793 IPR Does Not Preclude Relief Under Rule 60(b)**

Liquidia’s decision to pursue a successful IPR challenge to the ’793 patent does not preclude relief under Rule 60(b) as UTC suggests. BB36–37. In fact, *Marshall v. Board of Education, Bergenfield, N.J.*, 575 F.2d 417 (3d Cir. 1978), cited by UTC, makes clear that relief under Rule 60(b)(5) can be applied to modify judgments that are prospective or executory, like the § 271(e)(4)(A) injunction here, whereas judgments for “damages” are final and cannot be modified. BB37; *Marshall*, 575 F.2d at 425. Moreover, relief under Rule 60(b) was declined in *Marshall* and *Ackermann*, based on the litigant’s decision not to file an appeal. *Marshall*, 575 F.2d at 424 (“a motion made under Rule 60(b)(5) or (6) may not generally substitute for an appeal.”); *Ackermann v. United States*, 340 U.S. 193, 198 (1950) (“Petitioner made a considered choice not to appeal . . . . Petitioner cannot be relieved of such a choice because hindsight seems to indicate to him that his decision not to appeal was probably wrong[.]”). Similarly, in *Crossroads Equity Partners, LLC v. Dogmatic Products, Inc.*, a district court denied relief under Rule 60(b)(6), because, in choosing not to file affirmative defenses and counterclaims, defendants failed to show an exceptional circumstance. No. 3:11CV00069, 2014 WL 652139, at \*4 (W.D. Va. Feb. 19, 2014). Here, the exceptional circumstance

warranting the relief granted under Rule 60(b)(6) is the invalidation of the '793 patent and not Liquidia's IPR choice. Thus, neither *Marshall*, *Ackermann*, nor *Crossroads* stand for the broad proposition that relief under Rule 60(b)(5) or (6) is precluded in this case as UTC asserts.

Case law from this Court establishes that Rule 60(b) relief is available to Liquidia. In *Prism*, Sprint dropped its patent invalidity arguments prior to trial and proceeded only on non-infringement. *Prism*, 757 F. App'x at 982 (recognizing the parties stipulated before trial that Sprint may not argue the claims are allegedly invalid). Sprint later moved under Rule 60(b) to modify the judgment entered against it based on the finding of invalidity of the same patent in a separate case involving Prism and T-Mobile, which was granted by the district court. *Id.* at 982–83. This Court affirmed the district court's decision to grant Sprint relief under Rule 60(b) based on the subsequent invalidation of the same patent in a separate proceeding, despite the fact that Sprint made the deliberate choice not to litigate invalidity in its own case. *Id.* at 987. That same rationale applies here, and thus the district court did not abuse its discretion in granting Liquidia Rule 60(b) relief from judgment.

**F. The Balance of Equities Favors Affirming the District Court's Decision**

UTC strangely argues that the balance of equities is in its favor, relying on a district court case cautioning against excessive litigation. BB37–38 (relying on

*Orexo*, 371 F. Supp. 3d 175 at 186–87). But here, no such excessive litigation occurred because, as UTC points out, Liquidia asserted obviousness, and prevailed in the ’793 IPR, but did not argue obviousness before the district court. As such, Liquidia conserved judicial resources which puts the balance of equity in its favor.

Moreover, a careful look at the equities here warrants affirmance of the district court’s decision. “A patent by its very nature is affected with a public interest” and “[t]he far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.” *Blonder-Tongue*, 402 U.S. at 343 (quoting *Precision Instrument*, 324 U.S. at 816). Here, upholding the injunction would be “anomalous in the extreme in connection with patents this court has just held invalid.” *Mendenhall*, 26 F.3d at 1578; *see also ePlus*, 789 F.3d at 1354–55; *U.S. Ethernet*, 645 F. App’x at 1029–30. The ’793 patent has been held invalid and therefore, to continue to uphold an injunction based on a patent that no longer is enforceable would be *per se* inequitable and detrimental to the public interest. Further, “when the rest of the industry is not impeded by the patents, it seems manifestly unjust to . . . hold[] appellants liable and impair[] their ability to compete.” *Mendenhall*, 26 F.3d at 1583. If the district court’s decision is not affirmed, Liquidia stands to be the only company precluded by the invalid ’793 patent. *See Life Techs., Inc. v. Promega Corp.*, 189 F.R.D. 334, 338 (D. Md. 1999) (remarking that the defendant would be

the only competitor unable to practice the unenforceable patent). Accordingly, balancing the equities favors affirming the district court's Rule 60(b) decision.

## **VI. CONCLUSION**

For the foregoing reasons, Liquidia asks this Court to deny UTC's appeal and affirm the decision of the district court.

Dated: June 24, 2024

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d) and 32(a) and has been prepared using a proportionally-spaced typeface and includes 8,472 words.

Dated: June 24, 2024

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